SECTION 5. 510(K) SUMMARY

5. 510(K) SUMMARY

510k: k093521

510(k) SUMMARY
(per 21 CFR §807.92)

GDxPRO™

GENERAL INFORMATION

NOV 25 2009

Manufacturer:	Carl Zeiss Meditec Inc. 5160 Hacienda Drive Dublin, California 94568 (925) 557-4616 (phone) (925) 557-4259 (fax) Est. Reg. No. 2918630
Contact Person:	Judith A. Brimacombe, MA Director, Clinical/Regulatory Affairs Carl Zeiss Meditec Inc. 5160 Hacienda Drive Dublin, California 94568 (925) 557-4616 (phone) (925) 557-4259 (fax)
Date Summary Prepared:	October 23, 2009
Regulation Number:	21 CFR 886.1570
Classification name:	Ophthalmoscope, Laser Scanning
Classification:	Class II
Product Code:	MYC, HLI
Trade/Proprietary name:	GDxPRO™

PREDICATE DEVICE

Company:	Carl Zeiss Meditec, Inc.
Device:	GDx with ECC Retinal Nerve Fiber Layer Normative Database (K082016)

SECTION 5. 510(K) SUMMARY

INTENDED USE

The GDx is a confocal polarimetric scanning laser ophthalmoscope that is intended for imaging and three-dimensional analysis of the fundus and retinal nerve fiber layer (RNFL) in vivo.

INDICATIONS FOR USE

The GDx is a confocal polarimetric scanning laser ophthalmoscope that is intended for imaging and three-dimensional analysis of the fundus and retinal nerve fiber layer (RNFL) in vivo. The GDx and its GDx Variable Corneal Compensation (VCC) and GDx Enhanced Corneal Compensation (ECC) RNFL Normative Databases aid in the diagnosis and monitoring of diseases and disorders of the eye that may cause changes in the polarimetric retinal nerve fiber layer thickness. The GDx is to be used in patients who may have an optic neuropathy.

DEVICE DESCRIPTION

The GDxPRO is a confocal scanning laser ophthalmoscope comprising an opto-mechanical scanning laser head unit and a computer. The device employs Scanning Laser Polarimetry (SLP) to measure the Retinal Nerve Fiber Layer (RNFL) thickness using polarized light.

SUBSTANTIAL EQUIVALENCE

It is the opinion of Carl Zeiss Meditec, Incorporated that the GDxPRO is substantially equivalent to the GDx with ECC Retinal Nerve Fiber Layer Normative Database as it contains modifications to the predicate that do not raise questions of safety or efficacy. The indications for use statement for the GDxPRO is exactly the same as the indications for use statement for the predicate device cited in this application. A technological comparison demonstrates that the GDxPRO is functionally equivalent to the predicate device. Both devices are intended for imaging and three-dimensional analysis of the fundus and retinal nerve fiber layer (RNFL) in vivo.

Evaluation performed on the GDxPRO supports the indications for use statement and demonstrates that the device is substantially equivalent to the predicate device and does not raise new questions regarding safety and effectiveness.

SUMMARY

As described in this 510(k) Summary, all testing deemed necessary was conducted on the GDxPRO to ensure that the device is safe and effective for its intended use when used in accordance with its Instructions for Use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

Carl Zeiss Meditec, Inc.
c/o Underwriters Laboratories, Inc.
Mr. Ned E. Devine
Sr. Staff Engineer
333 Pfingten Road
Northbrook, IL 60062

NOV 2 5 2009

Re: K093521
Trade/Device Name: GDxPRO
Regulation Number: 21 CFR 886.1570
Regulation Name: Ophthalmoscope
Regulatory Class: II
Product Code: MYC
Dated: November 11, 2009
Received: November 13, 2009

Dear Mr. Devine:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/cdrh/mdr/ for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SECTION 4. INDICATIONS FOR USE STATEMENT

4. INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K093521

Device Name: GDxPRO™

Indications for Use:

The GDx is a confocal polarimetric scanning laser ophthalmoscope that is intended for imaging and three-dimensional analysis of the fundus and retinal nerve fiber layer (RNFL) in vivo. The GDx and its GDx Variable Corneal Compensation (VCC) and GDx Enhanced Corneal Compensation (ECC) RNFL Normative Databases aid in the diagnosis and monitoring of diseases and disorders of the eye that may cause changes in the polarimetric retinal nerve fiber layer thickness. The GDx is to be used in patients who may have an optic neuropathy.

Prescription Use __x__ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear, Nose and Throat Devices

510(k) Number K093521